UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

CITY OF CHARLESTON, WEST VIRGINIA, CITY OF HUNTINGTON, WEST VIRGINIA, CITY OF KENOVA, WEST VIRGINIA, and TOWN OF CEREDO, WEST VIRGINIA, municipal corporations, and other municipal corporations similarly situated,

Plaintiffs,

v. **Civil Action No. 2:17-cv-04267**

THE JOINT COMMISSION f/k/a THE JOINT COMMISSION ON ACCREDITATION OF HEALTH CARE ORGANIZATIONS, a not-for-profit organization, and its wholly-owned affiliate, JOINT COMMISSION RESOURCES, INC. d/b/a JOINT COMMISSION INTERNATIONAL, a not-for-profit organization,

Defendants.

MEMORANDUM OPINION AND ORDER

Pending are the plaintiffs' motion for leave to amend the complaint [ECF No. 43] and motion to vacate the judgment [ECF No. 44], each filed August 17, 2020. Additionally pending is the defendants' motion for leave to file a sur-reply [ECF No. 50], filed September 15, 2020, which motion is granted and the sur-reply attached thereto is deemed filed.

I.

This action, filed November 2, 2017, involved allegations against defendants The Joint Commission ("Joint Commission") and its wholly-owned subsidiary Joint Commission Resources, Inc. ("Joint Commission Resources") pertaining to their roles in the promulgation of Pain Management Standards (sometimes "PM Standards") used in accrediting health care organizations and other health care educational materials that purportedly led to the over-prescription of opioids to the detriment of the plaintiffs. See ECF No. 1 (Complaint). The plaintiffs, four West Virginia municipalities, brought three claims on behalf of themselves and others similarly situated, against the defendants: Count I, "Negligence, Gross Negligence and Willful Conduct"; Count II, "Unjust Enrichment"; and Count III, "Declaratory Judgment."[1] Id. at ¶¶ 143-59.

The defendants moved to dismiss the complaint pursuant to Federal Rule of Civil Procedure 12(b)(6) on January 29, 2018. ECF No. 19 (Joint Commission's Motion to Dismiss, or in the Alternative, Strike Class Action Allegations); ECF No. 21 (Joint Commission Resources' Motion to Dismiss). On July 20, 2020, the

[1] The court notes, as it did in its July 20, 2020 memorandum opinion and order, that Count III requested injunctive, as well as declaratory, relief. See ECF No. 41, at 76-78 (Memorandum Opinion and Order on the Motion to Dismiss).

court granted these motions by memorandum opinion and order and dismissed the complaint by judgment order. ECF No. 41; ECF No. 42 (Judgment Order). The seventy-nine-page memorandum opinion and order, found at ECF No. 41, offers a comprehensive discussion of the reasons for dismissing each claim, of which a brief summary is in order.

The court determined that Count I failed for several reasons relating to existence of a duty of care. ECF No. 41, at 33-62. Specifically, the court found that the economic loss doctrine applied to bar Count I inasmuch as the plaintiffs claimed economic losses and did not allege a "special relationship" or "privity of contract" with the defendants that might otherwise establish a duty of care. ECF No. 41, at 33-45.

The court also concluded that, notwithstanding the application of the economic loss doctrine, the plaintiffs failed to plead facts that could establish a duty of care inasmuch as they did not "plausibly show that defendants could reasonably foresee the harms described in the complaint." Id. at 45-53. In doing so, the court: observed that the defendants did not control the manufacture, distribution, or prescription of opioids; noted that the Pain Management Standards promulgated by the Joint Commission did not mention opioids or mandate their prescription; and found persuasive the defendants' argument that

"independent standards organizations like themselves do not generally owe a duty to the intended recipients of those standards, let alone third parties." Id. at 49-53. The court determined that additional policy considerations weighed against finding a duty of care inasmuch as, inter alia, doing so would expose the defendants to "a liability to the public at large with no manageable limits" and, relatedly, the learned intermediary doctrine counseled against finding such a duty. Id. at 53-60.

Regarding the gross negligence and reckless and willful conduct allegations found in Count I, the court concluded that "[t]he lack of foreseeability or duty of care precludes any showing that defendants were grossly negligent or conscious that the injury to plaintiffs was the likely or probable result of their conduct." Id. at 62.

The court also determined that the complaint did not adequately plead proximate cause, a necessary element of the Count I claims and the Count II unjust enrichment claim. Id. at 62-76. In so holding, the court summarized the chain of events that allegedly led to the plaintiffs' injuries alleged in the complaint:

> (i) After defendants promoted incorrect claims about the safety of opioids in promulgating the PM Standards and providing consulting services and accreditation to HCOs, (ii) HCOs [Health Care Organizations] adopted pain management protocols to ensure compliance with the PM Standards, (iii) licensed independent practitioners prescribed opioid medication based on these protocols and their own judgment, (iv) which led to a flood of opioid medication as well as a black market for addicts, and (v) this crisis forced plaintiffs to expend far greater resources and expenditures to combat addiction, respond to crime, and to support the numerous other costs alleged in the complaint.

Id. at 73-74. The court observed that the "[p]laintiffs' claims rely on various criminal actions of third parties, such as 'illegal drug trafficking,' 'criminal vagrancy,' 'stolen merchandise,' and 'property crimes,' as triggering a need for increased governmental services and remediation" and that the plaintiffs' claims are also dependent on the decisions of licensed independent medical professionals to overprescribe opioids to patients. Id. at 75. "[G]iven the numerous intervening events and parties standing between [the plaintiffs and the defendants]," the court concluded that the complaint, "failed to plead that the pain management strategies promoted by defendants proximately caused the widespread societal ills and costs suffered by plaintiffs." Id. at 74.

The court dismissed Count III, which sought declaratory and injunctive relief, inasmuch as this count did not assert an independent cause of action but simply sought

relief based on the underlying claims asserted in Counts I and II that were dismissed. Id. at 76-78.

The plaintiffs contemporaneously filed their two pending motions on August 17, 2020. ECF No. 43 (Motion for Leave to Amend the Complaint); ECF No. 44 (Motion to Vacate the Judgment). The motion to vacate the judgment states, in full:

> The plaintiffs respectfully move to vacate the judgment under Rule 59(e) or 60(b) so that the Court may consider the motion for leave to amend filed earlier today. The plaintiffs are seeking this relief only if the Court decides to grant the pending motion for leave to amend. If the Court denies our motion for leave to amend, then it should deny this motion as well.

ECF No. 44.

Attached to the motion for leave to amend is a copy of the plaintiffs' proposed amended complaint with three exhibits.[2] ECF No. 43-1 (Proposed Amended Complaint with Three Exhibits).

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[2] One of these exhibits, Exhibit 3, is an April 13, 2016 letter from Physicians for Responsible Opioid Prescribing to Dr. Mark Chassin, the president and CEO of the Joint Commission, relaying concerns about the Pain Management Standards' effect on opioid prescription and abuse. ECF No. 43-1, at 68-71 (April 13, 2016 letter from Physicians for Responsible Opioid Prescribing to Dr. Mark Chasson). The body of this letter was quoted in the original complaint, ECF No. 1, at ¶ 82.a-d, and referenced by the court in its July 20, 2020 memorandum opinion and order, ECF No. 41, at 15, 27-28, 48, 58, 59.

Thus, although the letter itself was not attached as an exhibit to the original complaint, its inclusion as an exhibit to the proposed amended complaint does not substantively present new allegations. Exhibits 1 and 2 present new materials and are discussed herein.

The motion first contends that the proposed amendments avoid the economic loss doctrine defects of the original complaint identified by the court inasmuch as the proposed amended pleading now alleges physical harm to the plaintiffs' property. ECF No. 43, at 2-3. According to the plaintiffs, several proposed amendments address this issue: (1) an allegation that "[m]unicipalities bear the cost of removing [opioid-addicted] residents, repairing or bulldozing the[ir abandoned] houses, and remediating the environmental pollutants that affect not only the lots on which the abandoned houses sit but also public property owned by the plaintiffs," ECF No. 43-1, at ¶ 143; (2) an allegation that "pollution associated with the opioid crisis also takes place in public streets, parks, and parking lots owned by the Municipalities, which have been damaged by human waste, used needles, and trash discarded by people who have entered the Municipalities to obtain drugs, and which the Municipalities bear the cost of cleaning up," id. at ¶ 144; an allegation of "deterioration in environmental quality," namely, that "Water supplies are harmed by the flushing of over-supplied opioids down toilets and drains, human waste, and trash"; and an allegation that physical damage associated with opioid-related pollution has "significantly reduced the aesthetic beauty of the municipalities and their surrounding environments," id. at ¶ 146.

The plaintiffs further contend, "The amended complaint also reiterates and clarifies the non-economic losses that the plaintiffs have suffered on account of the defendants' behavior, such as aesthetic harms and environmental pollution." ECF No. 43, at 3; see also ECF No. 49, at 2 (Reply in Support of Motion for Leave to Amend the Complaint). They cite one proposed amendment in support of this claim, an allegation that "they have suffered non-economic loss, including but not limited to disruptions to quality of life, losses of recreational opportunities, and significant community blight. In addition, plaintiffs allege devaluation of property, environmental pollution, and the elevation in the spread of infectious diseases."[3] ECF No. 43-1, at ¶ 41.

The plaintiffs also assert that the proposed amended complaint avoids the economic loss doctrine inasmuch as they now plead a "special relationship" with the defendants. ECF No. 43, at 4. The proposed amended complaint alleges that since the Joint Commission has "sought to enact through state

[3] Like the original complaint, the proposed amended complaint continues to allege the following damages characterized as "economic damages": "increased health care costs, insurance and self-insurance costs, health services costs, costs related to responding to and dealing with opioid-related crimes and emergencies, additional first responders, first responder and building department overtime, remediation of dilapidated and fire-damaged properties,[] criminal vagrancy, and other significant public safety costs." ECF No. 43-1, at ¶ 41.

legislatures" certain "statutory provisions" pertaining to health care accreditation,

> Plaintiffs and other governmental entities rely upon JCAHO to enact responsible standards and to enforce those standards in a responsible manner, including but not limited to standards related to pain management and opioid prescribing. Plaintiffs and other governmental entities further rely on JCAHO and JCR to adequately investigate the basis for any standards as well as any information JCAHO and JCR provide to health care organizations or physicians, or that JCAHO and JCR suggest or require that health care professionals provide to patients.

ECF No. 43-1, at ¶ 21. It further alleges:

> Plaintiffs did not see the need to impose or enforce their own standards on health care organizations and providers concerning the minutiae of pain management or opioid prescribing practices. As a consequence, Plaintiffs quite reasonably focused their regulatory and enforcement efforts on the unlicensed transfer of drugs, and rely on JCAHO to enforce its own standards concerning pain management.

Id. at ¶ 22. As a result of this "sacred trust" placed in the defendants, the proposed amended complaint alleges that "the public record reveals no local ordinances designed to regulate opioid prescriptions at those health care organizations." Id. at ¶ 23. These amended allegations, in the plaintiffs' estimation, establish a special relationship between them and the defendants. ECF No. 43, at 4.

The plaintiffs further posit that the proposed amendments, and attached exhibits, resolve the deficiencies identified by the court that relate to foreseeability as it

pertains to the existence of a duty of care. Id. at 4-5. On this point, the proposed amended complaint adds the following allegations:

> 85. In September 2006, Dr. Andrew Kolodny then the Vice Chair for Clinical Psychiatry in the Department of Psychiatry at Maimonides Medical Center, spoke at length with Kelly Podgorny, project director in JCAHO's Division of Standards and Survey Methods and the subject matter liaison for the Medication Management Standards, about the unintended consequences of broad based (rather than targeted) pain assessments as required by the JCAHO standard PC.8.10 "pain is assessed in all patients". Dr. Kolodny expressed his concerns about widespread addition [sic], including by those individuals who were not directly prescribed opioids under JCAHO standards. Dr. Kolodny also provided Ms. Podgorny with Exhibits 1 and 2 on September 20, 2006.
>
> 86. Dr. Kolodny explained to Ms. Podgorny that Exhibit 1 "documents a new epidemic of narcotic analgesic overdose deaths. [Exhibit 1] demonstrates that the overdose death rate increase has occurred in conjunction with a national trend toward more aggressive pain management."
>
> 87. Dr. Kolodny explained to Ms. Podgorny that Exhibit 2 "documents a new epidemic of narcotic analgesic abuse. Narcotic analgesics are now the second most commonly abused class of drugs in the United States. Like overdose deaths, the increase in abuse of narcotic analgesics also corresponds with the trend toward more aggressive management of pain that has occurred over the past decade."

ECF No. 43, at ¶¶ 85-87. Exhibit 1 referenced therein is a report entitled "Increasing deaths from opioid analgesics in the United States," published in 15 Pharmacoepidemiology and Drug Safety 618-27 (2006). ECF No. 43-1, at 55-64 (Exhibit 1 to Proposed Amended Complaint). Exhibit 2 referenced therein is a

May 21, 2004 article published in The NSDUH (National Survey on Drug Use and Health) Report, "an annual survey sponsored by the Substance Abuse and Mental Health Services Administration (SAMHSA)" of the United States Department of Health and Human Resources, entitled "Nonmedical Use of Prescription Pain Relievers." Id. at 65-67 (Exhibit 2 to Proposed Amended Complaint).

The plaintiffs further contend that they have "add[ed] allegations involving historical, empirical, and observational evidence that widespread opiate use leads to the very harms the plaintiffs allege in their complaint, and that as health care professionals, the defendants knew or should have known of this historical, empirical, and observational evidence." ECF No. 43, at 5. These added allegations that purportedly support foreseeability are as follows:

> 42. In promulgating, enforcing, and educating about the Pain Management Standards, Defendants, along with manufacturers and industry front groups, sought to overturn years of proven medical treatment practices dating to at least the start of the 20th Century, based on hard-learned lessons in China and the United States demonstrating that opiates are highly addictive and that their widespread use empirically and historically leads to a dizzying array of widespread damages to municipalities.
>
> 43. China, in 1839, was so distressed by Britain's importing of opium and the widespread damages associated with large-scale addiction that it went to war with Britain to prevent future imports. The damages inflicted on Chinese municipalities by

> **Britain's opium importing and promotion were similar to the damages suffered by Plaintiffs. Defendants, as health care experts, knew or should have known that widespread use of opiates leads to widespread impacts on municipalities.**
>
> **44. After the Civil War, doctors in the United States increased their prescribing of opium, causing widespread harm to municipalities similar to that suffered by Plaintiffs today. Defendants, as health care experts, knew or should have known that widespread use of opiates leads to widespread impacts on municipalities.**
>
> **45. As a result of this history, and the experience of health care professionals with those who are addicted to opiates, physicians were reluctant to prescribe opioids for fear of patient dependency and the broader consequences of widespread addiction. Thus, the damages Plaintiffs experienced were not only foreseeable, they were foreseen by those who had learned from history and experience. This was the prevailing wisdom throughout the medical profession prior to Defendants' efforts, in conjunction with pharmaceutical companies and others, to reverse nearly a century of medical knowledge and practice.**
>
> **46. According to the Smithsonian magazine's review of the post-Civil War opium crisis: Educating doctors was key to fighting the epidemic. Medical instructors and textbooks from the 1890s regularly delivered strong warnings against overusing opium. "By the late 19th century, [if] you pick up a medical journal about morphine addiction," says Courtwright, "you'll very commonly encounter a sentence like this: 'Doctors who resort too quickly to the needle are lazy, they're incompetent, they're poorly trained, they're behind the times.'" Defendants therefore knew or should have known as health care experts that this type of messaging is particularly effective in getting health care professionals to change the way patients are treated, and this is precisely the type of messaging Defendants used as part of their means of interfering with the treatment of pain.**

ECF No. 43-1, at ¶¶ 42-46 (alteration in Proposed Amended Complaint); see also id. at ¶ 176 ("Furthermore, Defendants

decided to reverse nearly a century of medical knowledge and practice. Defendants did so based on little or no research.").

Finally, the plaintiffs argue that the proposed amended complaint pleads additional facts to establish proximate cause and "rebut any assumption that physicians who prescribed the opioids relied on their 'independent medical judgment.'" ECF No. 43, at 6. On this point, the proposed amended complaint emphasizes the Joint Commission's "power and influence over medical practices." ECF No. 43-1, at ¶ 26. The plaintiffs allege that according to the Joint Commission itself, as admitted in an amicus brief in a case before the Supreme Court of the United States, "the Medicare Act of 1965, 42 U.S.C. § 1395bb, specifically provides that hospitals accredited by The Joint Commission, subject to certain limited exceptions, are deemed to be eligible to participate in the Medicare program." Id. at ¶ 24 (quoting a brief filed in Christie v. Adkins, No. 07-538, 2007 WL 4178499, at *2 (U.S. Nov. 21, 2007)).

The plaintiffs also quote a Karen Sibert, M.D., who wrote in 2014:[4]

> The Joint Commission has the power to decide whether the hospital deserves reaccreditation. Administrators, doctors, nurses, technicians, clerks, and janitors will be obsessed with the fear that the

[4] The plaintiffs give no context for this quotation other than that it was written by Sibert in 2014.

> reviewers will see them doing something that the Joint Commission doesn't consider a "best practice", and that they'll catch hell from their superiors. For you as a patient, any idea that your clinical care and your medical records are private becomes a delusion when the Joint Commission is on site. Their reviewers are given complete access to all your medical records, and they may even come into the operating room while you're having surgery without informing you ahead of time or asking your permission.
>
> [. . .]
>
> A few competitors, such as the international firm DNV GL, have started to make inroads in the lucrative business of accrediting hospitals, but for the time being the Joint Commission holds a virtual monopoly in the U.S.
>
> [. . .]
>
> . . . when the Joint Commission declares that evidence supports one treatment or medication as a standard of quality in healthcare, it forces clinicians to follow that recipe. If they don't, the hospital will score poorly on its next review.
>
> [. . .]
>
> Meanwhile, at my hospital, the level of tension is rising as we anticipate Joint Commission review within the next few weeks. Experienced nurses are pulled away from patient care to make mock review rounds. Department chairs circulate memos about minute details that could trip us up. One chairman concluded succinctly, "These people are not your friends."

Id. at ¶ 25 (alterations and emphasis in Proposed Amended Complaint). On a similar note, the plaintiffs allege, without citing to a particular instance, that "Defendants threatened physicians with potential malpractice liability if opioids were underprescribed and ridiculed physicians who believed opioids were addictive." Id. at ¶ 4.

Additionally, the plaintiffs claim that the proposed amended complaint alleges proximate cause inasmuch as it outlines the Joint Commission's enforcement of its Pain Management Standards. ECF No. 43, at 6. The proposed amended complaint describes the Joint Commission's surveys of health care facilities, which occur at least once every thirty-nine months and which health care professionals allegedly claim to cause "great anxiety." ECF No. 43-1, at ¶ 100. The proposed amended complaint alleges that Joint Commission surveyors "review patient charts to determine compliance with JCAHO standards, including the Pain Management Standards. Pain assessment and reassessment is reviewed, as well as how the health care provider responded to the pain assessment." Id. at ¶ 101. The plaintiffs further claim that Joint Commission surveyors interview healthcare professionals to "review the informational material provided to patients, expecting to see material similar to that produced or distributed by JCR and endorsed by JCAHO . . . ." Id. at ¶ 101.

It is also alleged that:

> [h]ealth care organizations risk their accreditation if their charts and staff interviews do not echo the JCR materials in terms of opioid treatment practices, e.g., prescribing or providing opioids with little concern that they are addictive, administering opioids in doses designed to make the patient free of pain, and providing patients materials like Health Facts for

> You that grossly misinform patients about the risks of opioids.

Id. at ¶ 102. According to the plaintiffs, "In areas where the health care provider fails to meet the JCAHO surveyor's view of how the pain management standard should be implemented, the health care organization is given 'requirements for improvement' and is expected to follow them in order to remain accredited." Id. at ¶ 103.

The proposed amended complaint includes the following quotation alleged to be found on the Joint Commission's website:

> JCAHO's influence extends well beyond the survey, however, as JCAHO describes on its website: Joint Commission accreditation does not begin and end with the on-site survey. It is a continuous process. Every time a nurse double-checks a patient's identification before administering a medication, every time a surgical team calls a "time out" to verify they agree they're about to perform the correct procedure, at the correct site, on the correct patient, they live and breathe the accreditation process. Every three months, hospitals submit data to the Joint Commission on how they treat conditions such as heart attack care and pneumonia – data that is available to the public and updated quarterly on qualitycheck.org. Throughout the accreditation cycle, organizations are provided with a self-assessment scoring tool to help monitor their ongoing standards compliance. Joint Commission accreditation is woven into the fabric of a health care organization's operations.

Id. at ¶ 105 (emphasis in Proposed Amended Complaint). The proposed amended complaint also states, without particularization, as follows:

> JCAHO surveyors began faulting health care providers for not addressing pain quickly enough through opioids, even though providing opioids in this manner was totally irresponsible. Because JCAHO and JCR also falsely claimed that opioids were essentially risk-free, JCAHO and JCR made what health care professionals previously believed was totally irresponsible seem like the responsible path.

Id. at ¶ 106.

The plaintiffs assert that there was no undue delay in seeking to amend the complaint after a ruling on the motions to dismiss inasmuch as they had no indication how the court would rule prior to the entry of the memorandum opinion and order on July 20, 2020, and they "reasonably believed the facts the defendants claimed in their reply were not in the complaint were fair inferences from what was alleged." ECF No. 49, at 4-5. Moreover, they assert that delay alone is insufficient reason to deny a motion to amend absent prejudice to opposing parties, which, they claim, does not exist under the present circumstances. Id. at 5.

The defendants argue that amendment is futile and should be denied inasmuch as the proposed amended complaint "fails to satisfy the requirements of the federal rules," namely, Federal Rule of Civil Procedure 12(b)(6). ECF No. 48, at 7 (Response to Motion for Leave to Amend the Complaint) (quoting Friend v. Remac America, Inc., 924 F. Supp. 2d 692, 696 (N.D. W. Va. 2013)). Specifically, the defendants argue that

the plaintiffs cannot overcome the economic loss doctrine inasmuch as the new allegations pertaining thereto are merely repackaged iterations of their prior "community blight" and "disruptions to quality of life" allegations and the plaintiffs offer no caselaw in support of their position that such allegations are non-economic losses. Id. at 8. They further contend that the harm to water supplies allegation is not a well-pled fact entitled to an assumption of truth and that, notwithstanding this point, it contrasts with their theory of recovery, which is based on overconsumption of opioids, inasmuch as it alleges that residents have been flushing over-supplied opioids. Id. at 9, 9 n. 2. And insofar as the plaintiffs now allege harm to streets, sidewalks, and common areas, the defendants assert that such allegations are speculative and conclusory. Id.

The defendants argue that the new allegations do not establish a "special relationship" such that the economic loss problem may be overcome inasmuch as the defendants' alleged conduct has not affected the plaintiffs differently from society in general. Id. at 10. The defendants also posit that a special relationship must be narrowly defined and the new "special relationship" alleged in the proposed amended complaint, which pertains to nationwide governmental reliance on

the Joint Commission's standards and enforcement of such standards, cannot be narrowly defined if it is as widespread as claimed. Id. at 11.

As to foreseeability, the defendants note the allegations relating to Kolodny's 2006 communications with the Joint Commission as well as the allegations pertaining to historical damages to municipalities in the United States and China. Id. They assert, however, that such allegations "miss the mark" on foreseeability inasmuch as they do not show that the plaintiffs were invited to rely upon the Joint Commission's Pain Management Standards. Id. at 12. Additionally, the defendants contend:

> no additional allegations (and certainly not those in the Proposed Amendment) can change the nature of the parties' relationship – that of two independent standards organizations and third-party government entities. As this Court previously held, independent standards organizations do not owe a duty to intended recipients of their standards, let alone third parties like Plaintiffs.

Id.

The defendants further contest the sufficiency of the proposed amended complaint's new allegations pertaining to proximate cause. Id. at 12-14. Insofar as the plaintiffs have attempted to allege that prescribing physicians did not exercise independent judgment, the defendants claim, "None of the new

allegations explains how Defendants 'overcame' physicians' independent medical judgment." Id. at 13. Assuming this were the case, however, the defendants assert that numerous other intervening factors, including unnecessary over-prescription of opioids, drug trafficking, criminal vagrancy, and property crimes, contributed to the injuries alleged by the plaintiffs, precluding proximate cause. Id. at 13-14.

The defendants additionally contend that amendment should be denied inasmuch as the plaintiffs were dilatory in their efforts to seek amendment and amendment would prejudice them. Id. at 14-17. They contend that the plaintiffs were dilatory inasmuch as they should have moved for leave to amend the complaint rather than oppose the motions to dismiss during the two-and-a-half-year window the motions were pending. Id. at 15. They also observe that such action would have been possible since the new facts contained in the proposed amended complaint were available to the plaintiffs at the outset of the litigation. Id. at 16. The defendants further contend that "[a]llowing Plaintiffs leave to amend under these circumstances would both delay final justice and significantly prejudice Defendants by forcing them to re-start their legal defense nearly three years after suit was first filed." Id. at 4.

II.

Federal Rule of Civil Procedure 15(a)(1) allows a party to amend a pleading once as a matter of course "within 21 days after serving it," or, "if the pleading is one to which a responsive pleading is required, 21 days after service of a responsive pleading or 21 days after service of a motion under Rule 12(b), (e), or (f), whichever is earlier." Rule 15(a)(2) provides that "[i]n all other cases, a party may amend its pleading only with the opposing party's written consent or the court's leave. The court should freely give leave when justice so requires."

The Fourth Circuit has "interpreted Rule 15(a) to provide that 'leave to amend a pleading should be denied only when the amendment would be prejudicial to the opposing party, there has been bad faith on the part of the moving party, or the amendment would have been futile.'" Laber v. Harvey, 438 F.3d 404, 426 (4th Cir. 2006) (en banc) (quoting Johnson v. Oroweat Foods Co., 785 F.2d 503, 509 (4th Cir. 1986)). "Futility is apparent if the proposed amended complaint fails to state a claim under the applicable rules and accompanying standards . . . ." Katyle v. Penn Nat'l Gaming, Inc., 637 F.3d 462, 471 (4th Cir. 2011).

"[A] post-judgment motion to amend is evaluated under the same legal standard as a similar motion filed before judgment was entered — for prejudice, bad faith, or futility." Laber, 438 F.3d at 427 (citing Foman v. Davis, 371 U.S. 178, 182 (1962); Johnson, 785 F.2d at 509-10). Although a post-judgment motion to amend may not be granted unless it is appropriate to vacate the judgment under Rule 59(e) or Rule 60(b), the court "need only ask whether the amendment should be granted, just as it would on a prejudgment motion to amend pursuant to Fed. R. Civ. P. 15(a)." Katyle, 637 F.3d at 471.

III.

The July 20, 2020 memorandum opinion and order identified four independent reasons that the negligence claim asserted in Count I should be dismissed for failure to state a claim, three of which (the economic loss doctrine, foreseeability, and policy considerations) pertained to the existence of a duty of care and one of which pertained to proximate cause. The memorandum opinion and order likewise found that the gross negligence and reckless and willful conduct claims contained in Count I should be dismissed inasmuch as the complaint did not adequately plead a duty of care generally or foreseeability. Additionally, the court found that the unjust enrichment claim alleged in Count II failed for lack of

proximate cause. Finally, the court found that dismissal of Count III was warranted inasmuch as dismissal of Counts I and II was appropriate.

At bottom, the question of whether the plaintiffs should be granted leave to amend their complaint centers on whether the proposed amended complaint adequately addresses each independent deficiency warranting dismissal of Count I and Count II. The proposed amended complaint does not accomplish this task for several reasons.

First, the proposed amended complaint does not adequately address foreseeability as it pertains to the existence of a duty of care. On foreseeability, the plaintiffs bring new allegations describing Kolodny's 2006 communications with the Joint Commission and historical examples. None of these allegations address the foreseeability problems identified in the court's analysis. They do not address the court's finding that "[u]nlike the manufacturer and distributor defendants in Summit County, defendants here had no control or responsibility over the manufacturing or distributing of opioids. Although the 2001 NPC Monograph and 2001 TJC Monograph refer to opioids, the PM Standards themselves did not even mention opioids or mandate opioid prescriptions." ECF No. 41, at 49. Indeed, the plaintiffs acknowledge as much by the

allegation in its complaint at paragraph 56 which is set forth in its proposed amended complaint at paragraph 72: "JCAHO's Pain Management Standards never overtly required opioid treatments." An exception to the absence of mention of opioids in the PM Standards applies in that, as alleged in the complaint at paragraph 86, "In 2016, JCAHO . . . reexamined the Pain Management Standards and in July 2017 issued new Standards to take effect in January of 2018," as a result of which Standard LD.04.03.13 prescribed as follows:

> Standard LD.04.03.13
> Pain assessment and pain management, including safe opioid prescribing is identified as an organizational priority for the hospital.

R^3 Report, The Joint Comm'n (Aug. 29, 2017).

As the defendants correctly note, the proposed amendments do not address the foreseeability analysis' emphasis on caselaw indicating that independent standards organizations like the defendants do not generally owe a duty of care to the intended recipients of those standards, i.e., the health care organizations in this action, let alone third parties like the municipality plaintiffs. Id. at 49-53 (citing In re Welding Fume Prod. Liab. Litig., 526 F. Supp. 2d 775, 799, 800 n.114 (N.D. Ohio 2007); Evenson v. Osmose Wood Preserving, Inc., 760 F. Supp. 1345, 1349 (S.D. Ind. 1990); Gunsalus v. Celotex Corp., 674 F. Supp. 1149, 1157 (E.D. Pa. 1987); Klein v. Council of

Chem. Ass'ns, 587 F. Supp. 213, 225 (E.D. Pa. 1984); Meyers v. Donnatacci, 531 A.2d 398, 403 (N.J. Super. Ct. 1987); Bailey v. Edward Hines Lumber Co., 719 N.E.2d 50, 178 (Ill. App. Ct. 1999)).

Additionally, the court observes that the July 20, 2020 memorandum opinion and order quoted Syllabus Point 3 of Sewell v. Gregory, 371 S.E.2d 82, 83 (W. Va. 1988), in which the Supreme Court of Appeals of West Virginia held:

> The ultimate test of the existence of a duty to use care is found in the foreseeability that harm may result if it is not exercised. The test is, would the ordinary man in the defendant's position, knowing what he knew or should have known, anticipate that harm of the general nature of that suffered was likely to result?

The court likewise quoted Robertson v. LeMaster, 301 S.E.2d 563, 568 (W. Va. 1983), for the proposition that "[d]ue care is a relative term and depends on time, place, and other circumstances. It should be in proportion to the danger apparent and within reasonable anticipation." These quotations make clear that foreseeability does not gauge whether the defendants could foresee any harm resulting from their conduct, but rather involves an inquiry of whether the defendants could foresee a harm similar to that actually suffered.

Neither the Kolodny nor the historical allegations of the proposed amended complaint remotely relate to the physical

harms now alleged by the plaintiffs. There is no allegation that Kolodny told the Joint Commission about public property damage and pollution that could conceivably impact municipalities. And there is no allegation that municipalities in China and the United States experienced physical harms, such as water pollution due to opioids flushed down toilets or other opioid-related pollution on publicly owned streets and sidewalks, after a rise in opium consumption and addiction during the Nineteenth Century – there are only vague allusions by plaintiffs to that which they call "a dizzying array of widespread damages to municipalities," "damages . . . similar to the damages suffered by Plaintiffs," and "widespread harm to municipalities." ECF No. 43-1, at ¶¶ 43-44.

And to the extent the economic damages, "community blight," "disruptions to quality of life," "losses of recreational opportunities," aesthetic harms, and related injuries alleged, id. at ¶¶ 41, 146, are not barred by the economic loss doctrine since obscure physical harms to the plaintiffs' properties are also alleged,[5] the Kolodny and historical allegations still fail to relate to these harms. The

[5] The court need not decide whether the proposed amended complaint cures all economic loss doctrine problems identified in the July 20, 2020 memorandum opinion and order, see ECF No. 41, at 33-45, inasmuch as it is clear that Count I remains deficient for the other reasons discussed herein.

Kolodny-related allegations have nothing to do with harms to municipalities, and the historical harm examples are so vague that they do not even allege that Chinese and American municipalities suffered "harm of the general nature of that suffered" by the plaintiffs according to the proposed amended complaint. Syl. Pt. 3, Sewell, 371 S.E.2d at 83.

Second, the proposed amended complaint does not adequately address the policy considerations discussed in the July 20, 2020 memorandum opinion and order. In the memorandum opinion and order, the court quoted Robertson, 301 S.E.2d at 568, for the proposition, "Beyond the question of foreseeability, the existence of duty also involves policy considerations underlying the core issue of the scope of the legal system's protection." ECF No. 41, at 53. "These policy factors 'include the likelihood of injury, the magnitude of the burden of guarding against it, and the consequences of placing that burden on the defendant.'" Id. (quoting Robertson, 301 S.E.2d at 568).

With regard to the latter two factors, the court found as follows:

> [T]he consequences of imposing this duty on defendants would expose them to a liability to the public at large with no manageable limits. Aikens noted that "[e]ach segment of society will suffer injustice, whether situated as plaintiff or defendant, if there

> are no finite boundaries to liability." 541 S.E.2d at 592. The "[c]ourt's obligation is to draw a line beyond which the law will not extend its protection in tort, and to declare, as a matter of law, that no duty exists beyond that court-created line." Id. Several intermediaries stand in between plaintiffs and defendants, including the HCOs responsible for issuing their own pain management protocols, the medical practitioners responsible for issuing opioid treatments, as well the pharmaceutical manufacturers, distributors, and retailers who bring the opioids to market in the first place.

Id. at 55 (second alteration in the July 20, 2020 memorandum opinion and order). The court similarly found that the learned intermediary doctrine, which restricts the liability of prescription drug and medical device manufacturers to patients if they warn practitioners of the dangers associated with their products, weighed against finding a duty, "where the independent medical practitioners [in this case] assumed ultimate responsibility for advising patients about opioid risks and, compared to the opioid manufacturers themselves, defendants are at least one step further removed from the individual patients." Id. at 57. Indeed, the court found the plaintiffs' acknowledgement that "[h]ealth care professionals are capable of using their clinical judgment to determine when to assess patients for pain" to be indicative of a "corollary principle that physicians exercise their independent clinical judgment in patient evaluations, including when deciding whether to

prescribe opioid treatments." Id. at 59 (alteration in the July 20, 2020 memorandum opinion and order).

These points formed the basis of the court's conclusion that "[t]he enormous scale of the opioid crisis has reached almost every corner of society, but the court must draw a line somewhere. It cannot extend a duty to the full constellation of individuals and communities who have suffered in the wake of the opioid crisis without running afoul of Aikens." Id. at 60. Nothing offered in the proposed amendments refutes this conclusion. As the defendants argue, the new allegations pertaining to the Joint Commission's efforts to enforce their standards through surveys and otherwise do not demonstrate that practitioners at accredited health care organizations had their independent medical judgments overcome by those of the Joint Commission. Indeed, the plaintiffs effectively allege, through the citation to Exhibit 3 in paragraph 108.b, that "[h]ealth care professionals are capable of using their clinical judgment to determine when to assess patients for pain." ECF No. 43-1, at ¶ 108.b.

And the court's general policy reasoning relating to intermediaries remains unchanged. This case does not involve claims alleged by a plaintiff against a prescribing physician or drug manufacturer defendant. Between the plaintiffs and the

defendants stand the opioid manufacturers, opioid distributors, accredited health care organizations, opioid prescribers who possess independent medical judgment, and patients and other third-parties who must commit additional acts, such as polluting, to cause the harms alleged by the plaintiffs. Courts have an obligation to draw lines beyond which no duty of care exists. Aikens, 541 S.E.2d at 592. From a policy standpoint, the proposed amended complaint continues to assert a duty of care that falls beyond such a line.

Third and similarly, the proposed amended complaint fails to adequately plead proximate cause. The new allegations concerning the power of the Joint Commission over practitioners at accredited health care organizations and the enforcement of standards through surveys and related activities could not, if true, establish that the independent medical judgment of prescribing practitioners was overborne by the defendants. And even if they could establish this, there remains an exceedingly long chain of independent actions between the defendants' conduct and the harms alleged by the plaintiffs, which includes, inter alia, opioid manufacture and distribution, the acquiescence of health care organizations to a course of conduct that transcends the PM Standards promulgated by the defendants, the over-prescription of opioids by prescribing health care

professionals, the rise of a black market for opioids, and harms such as pollution, vagrancy, and community blight resulting from the use of opioids unnecessarily prescribed or obtained through illegal means. Simply put, the proposed amended complaint does not, and cannot, adequately plead proximate cause due to the plethora of independent actions that lie between the alleged conduct of the defendants and the injuries allegedly suffered by the plaintiffs.

Inasmuch as foreseeability, policy considerations, and proximate cause problems remain outstanding despite the new allegations raised in the proposed amended complaint, amendment of Count I would be futile. And inasmuch as the unjust enrichment claim found in Count II also requires a showing of proximate cause, amendment thereof would also be futile. Since amendment of the two substantive counts would be futile, the court finds that the July 20, 2020 memorandum opinion and order's rationale for dismissing Count III's requests for declaratory and injunctive relief stands.

Inasmuch as it is clear that amendment would be futile for the foregoing reasons, the court need not address the undue delay and prejudice arguments of the defendants.

IV.

Accordingly, it is ORDERED that:

1. The defendants' motion for leave to file a sur-reply (ECF No. 50) be, and it hereby is, GRANTED and the sur-reply attached thereto is deemed filed.

2. The plaintiffs' motion for leave to file an amended complaint (ECF No. 43) be, and it hereby is, DENIED.

3. The plaintiffs' motion to vacate the judgment (ECF No. 44) be, and it hereby is, DENIED.

The Clerk is directed to transmit copies of this memorandum opinion and order to all counsel of record and any unrepresented parties.

ENTER: September 20, 2021

John T. Copenhaver, Jr.
Senior United States District Judge